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[Docket No. 98P-0504]
Dockets Management Branch (HFA)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sirs:

I am writing to inform you that I have successfully developed patented pasteurization technology for proteinaceous foods – including raw molluscan shellfish – that will initially be used on a commercial basis to pasteurize shell eggs in order to eliminate *Salmonella* (including *Salmonella enteritidis*) inexpensively without cooking or loss of raw egg functionality. The U.S. Patent and Trademark Office has allowed my patent application and the issue fees have been paid. Within the next few months, I will receive my patent number.

The aspect of this pasteurization technology dealing with in-shell eggs has been licensed to Pasteurized Eggs, L.P. My technology has been incorporated into a commercial sized machine as depicted in the attached brochure. At present, one machine is completed and two more are in the process of being built. Upon completion of the next two machines, a major East Coast egg supplier will make the introduction of pasteurized in-shell eggs to the American public later this year.

As I previously stated, my technology is able to eliminate *Salmonella enteritidis* and other species of *Salmonella* inexpensively without changing the organoleptic qualities, or functions of the raw egg. The eggs qualify to be labeled PASTEURIZED and to carry the new USDA shield stating "CERTIFIED PASTEURIZED".

As currently utilized, this technology achieves a 5-log kill of *Salmonella* to the center of the yolk with no noticeable sensory effect to the raw eggs. As specified in my currently allowed U.S. and international patent applications, post-harvest processing of raw molluscan shellfish to reduce naturally occurring bacteria such as *Vibrio vulnificus* and *Vibrio parahaemolyticus* to nondetectable levels is fully achievable. This same technology that is currently employed in shell egg pasteurization has direct application to raw molluscan shellfish. Machines of new design or relatively simple machine modifications of existing machines to accommodate raw molluscan shellfish are straightforward and easily achievable propositions that I plan to pursue under the auspices of the Pasteurized Protein Corporation, a company that is currently being formed to expand the applications of my pasteurization technology.

To that end, I am currently working with Kansas State University who are in the process of conducting verification studies on raw beef and poultry products. As soon as the Pasteurized Protein Corporation is legally formed in May of 1999, I will expand my verification studies to include raw in-shell oysters in order to present the results to the

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FDA for recognition and labeling guidance, and be better prepared to license my pasteurizing technology to others, much as I have already done for eggs.

Whether or not I actually license my technology, though, will depend, in large part, on the FDA's final decision as to the Citizen's Petition currently before the agency. I have investigated the current marketplace and feel there would only be ample room for competing post-harvest technologies once the industry is required by regulation to meet stricter consumer safety standards than are currently in place. I base this on common business sense because the domestic oyster industry is presently in clear decline and not ripe for multiple value added products. On the contrary, the industry as a whole needs value added to it through better health regulations. In the 1990's oyster safety has become suspect in the mind of much of the public. However, I believe that consumer demand for raw oysters would eventually rise with public awareness of protective safety standards being instituted for what is currently a menu option requiring a "certain" attitude on the part of the consumer.

Our initial estimates as to the incremental cost to seafood wholesalers of post-harvest processed oysters or other molluscan shellfish would range from pennies to a dime per mollusk. The incremental cost would depend on several factors that I am currently investigating more fully.

In closing, let me just add that I have fifteen commercially successful patents to my credit over the past thirty years, including the cooking computers most commonly used today in commercial kitchens throughout the world. At present I am most excited with my protein pasteurization technology for the simple reason that it can reliably prevent food borne illnesses, save lives and possibly extend product shelf life.

As we learn more about the pathogen risks associated with human ingestion of proteins, it only seems appropriate that food processors and health regulators work together toward lessening these risks.

If you have any questions, please feel free to contact me at any time.

Truly yours,

A handwritten signature in cursive script, reading "Louis Polster". The signature is written in dark ink and is positioned above the printed name.

Louis Polster

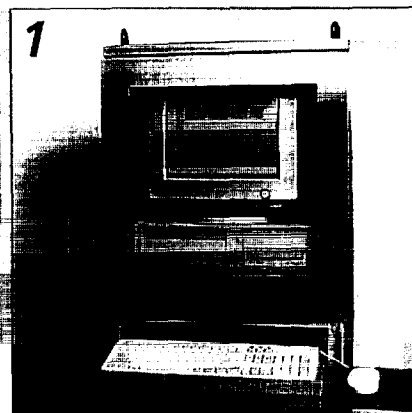
FPS offers commercial scale machine for shell egg pasteurization

Responding to the international threat to the shell egg industry caused by *Salmonella enteritidis* (Se) and the heightened public concern over food safety, FPS has achieved a major breakthrough in pasteurizing shell eggs inexpensively without cooking or loss of functionality. In cooperation with Pasteurized Eggs, L.P., a New Hampshire, U.S.A. company, owner of the pasteurization technology, FPS has completed development of a machine that pasteurizes shell eggs to specifications set by the United States Food and Drug Administration (FDA). The eggs qualify to be labeled PASTEURIZED and to carry the New USDA Shield stating "CERTIFIED-PASTEURIZED". With this revolutionary technology, the inevitable higher safety requirements for shell eggs are fully satisfied.

A new era for shell eggs

The highly sophisticated FPS Pasteurizer, Hydro-175, destroys salmonella in an egg to meet the new United States Food and Drug Administration standards of an impressive 5-log kill.

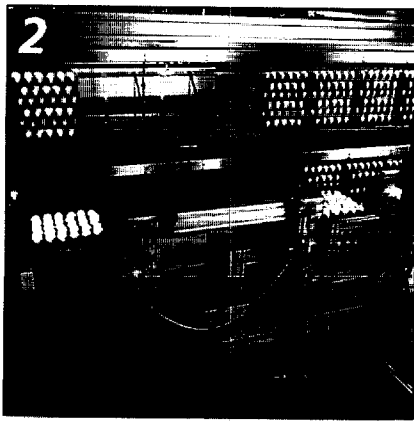
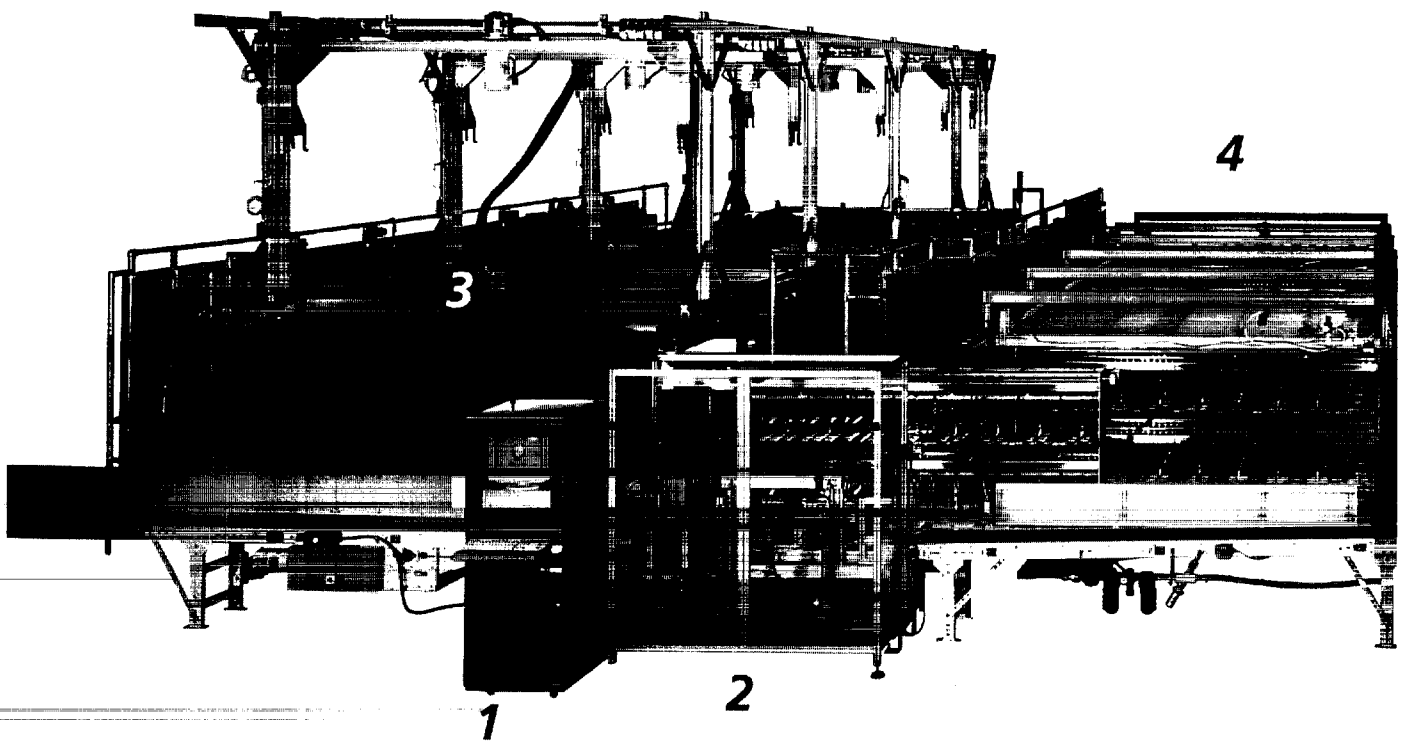
The HYDRO-175 meets the highest standards for food safety in shell eggs during processing. The machine is the first in the industry to deliver eggs with a maximum internal Yolk



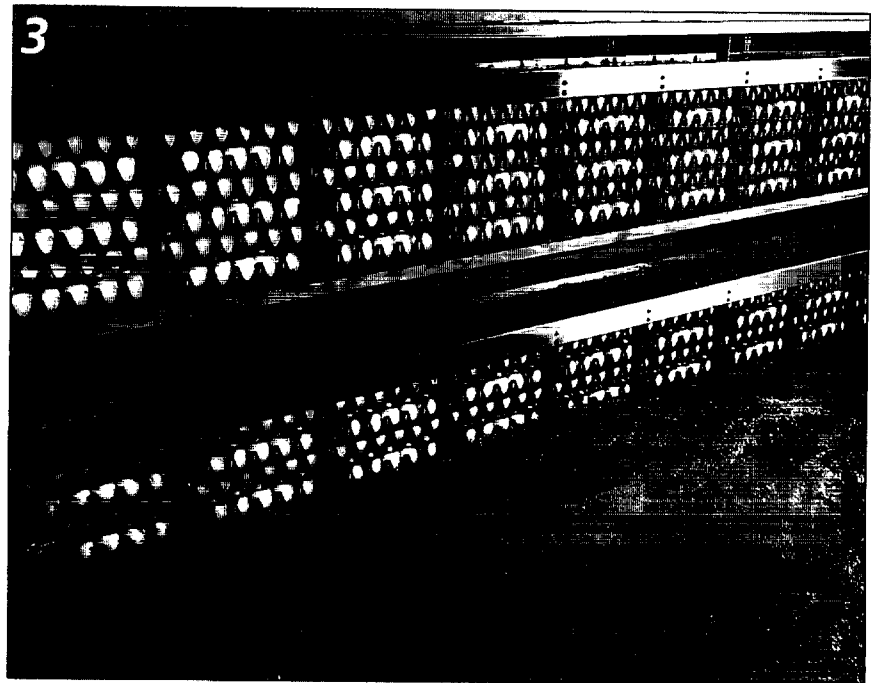
A special PC controls the entire process fully automatically.

temperature of 45°F (7°C) in response to the growing needs for safety derived from refrigeration. After pasteurization, the eggs retain all of **the characteristics of a fresh raw egg in their appearance, taste and functionality.** There is no reduction to shelf life. Egg quality is preserved. Public safety is essentially a certainty.





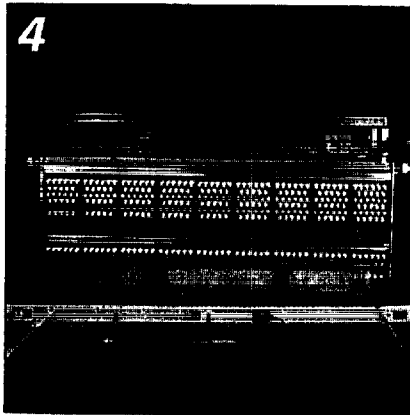
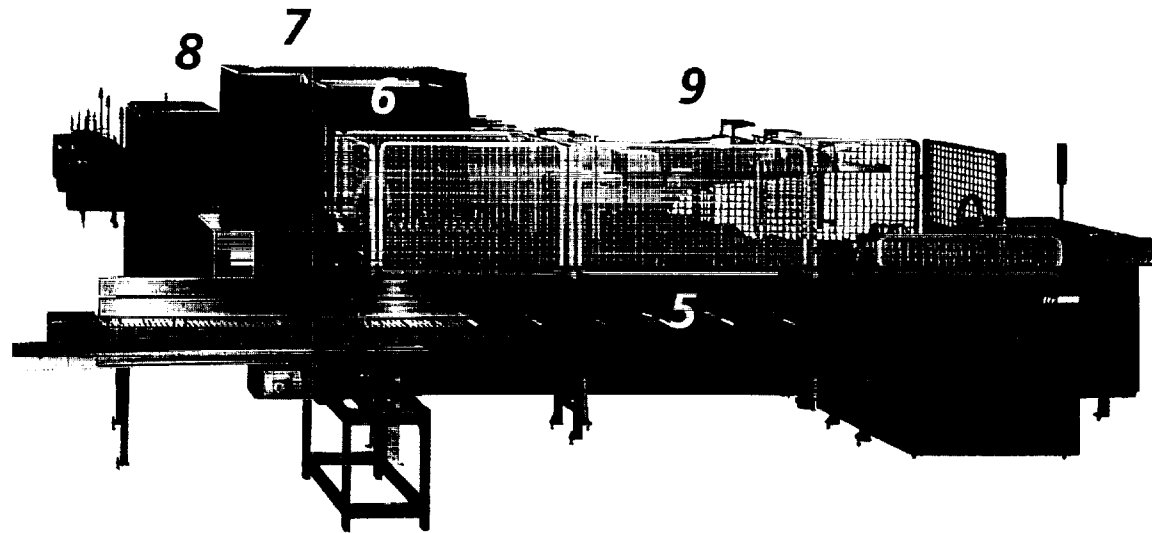
Loading and unloading of egg carriers.



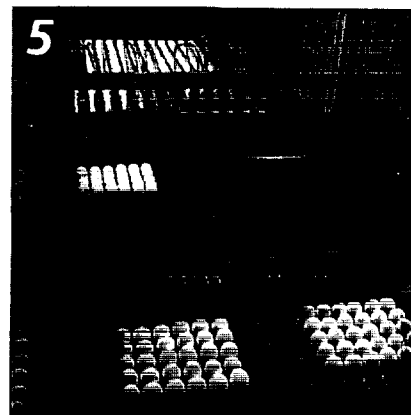
Highly advanced patented technology controls water bath temperatures to an accuracy of 0.1°F (0.18°C). The shells receive a protective,

sealant. The sealant guarantees continued safety and preservation of quality. Eggs exit at a maximum internal temperature of 45°F (7°C).

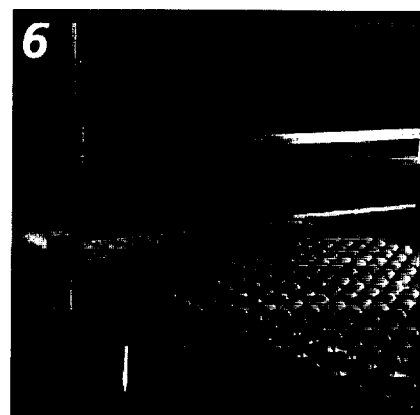
Egg Handling Systems **FHS**



The return conveyor accommodates multiple carriers for uninterrupted operation.



The eggs are transferred to a conveyor feeding the multiloader.



Eggs are air dried prior to packaging.



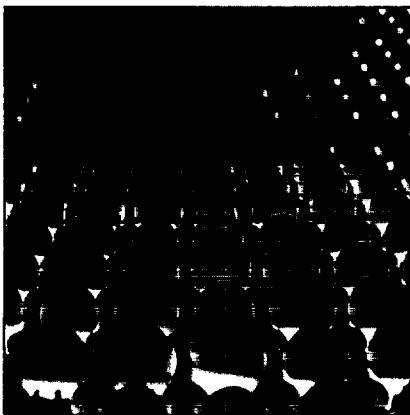
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Egg Handling Systems **FPS**

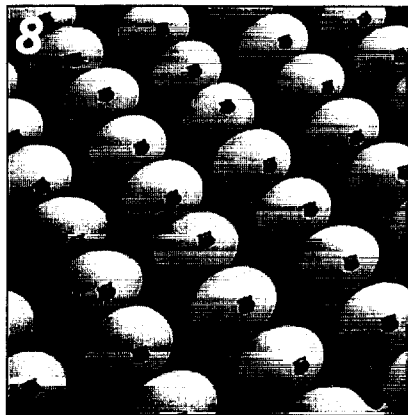
The HYDRO-175 pasteurizes eggs at the rate of **175 cases per hour** with great economic efficiency and product consistency while meeting the standards recently set for pasteurization of shell eggs by the U.S. FDA.

Numerous quality control systems are built into the design which is fully automated and computerized. **It is operator friendly and processes eggs with a minimum of waste and breakage.** Additionally, the pasteurizer applies a special sealant to the shell. As a result the quality and the freshness of the eggs are preserved over a long period of time.

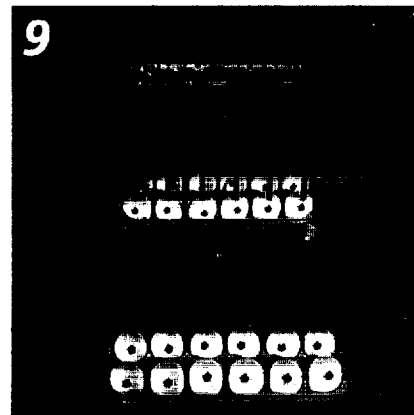
By the development of the HYDRO-175, FPS again has demonstrated its leadership role in servicing the shell egg industry with machines that will open new markets and create greater producer profitability. By being quick to recognize and respond to the needs of the marketplace for new safety standards in eggs, FPS has provided the producer with the ability to make eggs as pure and safe as they can be. **The market most assuredly will respond. The time proven benefits of pasteurization, now available to fresh shell eggs, is revolutionary and truly present an enormous business opportunity.**



After the pasteurization process, eggs are candled for imperfections.



The pasteurization technology qualifies the processed eggs to receive the USDA Shield stating "Certified-Pasteurized".



Pasteurized eggs are packaged automatically.

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